REMARKS

Applicant herein traverses and respectfully requests reconsideration of the rejections of the claims in view of the following remarks.

Claims 34 and 41 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,256,154 (Liebert et al.) in view of U.S. Patent No. 3,709,365 (Czaplinski et al.).

In particular, the Examiner states:

> "Liebert et al. discloses a pharmaceutical package as best seen in figure 1, which comprises a closed polypropylene bottle/barrel (2) in which is disposed a solution (12), the solution comprises a pharmaceutical product (column 1, lines 8-16), wherein the solution does not fill the bottle completely and some air is disposed in the bottle (column 3, lines 40-45), autoclaving the package (column 5, lines 15-36), after the autoclaving of the package, the package suffers no deformation, does not shrink and does not explode, and where the package retains a sufficiently high squeezability to dispense the solution as best seen in Figure 1, a plastic nozzle tip (24) for dispensing the solution. Liebert et al. lacks after autoclaving at least 121°C and for at least 20 minutes. Czaplinski et al. teaches the use of autoclaving a polypropylene at about 115°-125°C from 20-30 minutes.
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> It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the teaching of Czaplinski et al. into the package of Liebert et al., as such, in order to treat a material that can withstand autoclaving at a temperature 121°C for at least 20 minutes, as taught by Czaplinski et al. (column 2, lines 49-53)."

The Examiner further states at Page 7:

> "In response to applicant's argument that Liebert does not disclose a polypropylene bottle, but rather describe a syringe, and a syringe differs from a bottle. These arguments are not well founded. MPEP 2111 claim Interpretation Broadest Reasonable Interpretation states: "claims must be given their broadest reasonable interpretation." During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification." According to Microsoft Bookshelf's Dictionary, the definition of a "barrel" encompasses "a large, cylindrical container or a cylinder that contains a movable piston." In Figure 1, Liebert shows a polypropylene barrel/bottle 20 for holding a product 12. Since the claimed terminology is broad enough to encompass "a large, cylindrical container or a cylinder that contains a movable piston." Therefore, the bottle/barrel of Liebert et al. meets at least one of the above definitions. Then, the claim limitation is fairly met."

Applicant disagrees with the Examiner's conclusion and respectfully submits that the combined cited references do not make obvious the claimed subject matter as defined in independent Claim 34 for the reasons stated below.

First, Applicant acknowledges that in interpreting claim language under MPEP §2111 "claims must be given their broadest reasonable interpretation" and duly notes the Examiner's quote of a definition of a barrel as encompassing "a large, cylindrical container or a cylinder that contains a movable piston." MPEP §2141.02, however, indicates that when ascertaining the differences between the prior art and the claims at issue, not only must the claimed invention be considered as a whole, but also the prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. To this end, the statements made by the Examiner at Page 2 when discussing the disclosure of Liebert et al. and at Page 7 when discussing the interpretation of the term "barrel", clearly show that he is not considering the claimed invention or the Liebert et al. disclosure as a whole, but instead has chosen certain features of the prior art and has compared them to certain features of the claimed invention. Further, the Examiner has asserted that the syringe of Liebert et al. possesses particular features, which features are not described for the syringe of Liebert et al. Applicants respectfully submit that the presently claimed pharmaceutical package viewed as a whole is completely different from the syringe described by Liebert et al.

As noted above, the Examiner at Page 2 (point 3), indicates that Liebert discloses a pharmaceutical package which comprises a closed polypropylene bottle/barrel (2) in which is disposed a solution (12) comprising a pharmaceutical product, wherein the solution does not fill the bottle completely and some air is disposed in the bottle. The Examiner further indicates with respect to Liebert et al. that the package is autoclaved, and after autoclaving the package suffers no deformation, does not shrink or explode, and retains a sufficiently high squeezability to dispense solution.

It is noted, however, that the barrel described in Liebert et al. comprises other key features that the Examiner has failed to mentioned. The barrel is actually a syringe that is prefilled with a pharmaceutical product. The pre-filled syringe described by Liebert et al. (see e.g., Figure 1; column 2, lines 12-34; column 4, lines 19-45; and Claim 1) comprises a barrel (20) having a nozzle at the distal end and an open or proximal end, a one-way valve (30) removably mounted onto the nozzle, a slidable plunger (5) in the barrel located in the proximity of the proximal end, an endcap removably connected to the proximal end of the barrel, and an endcap restraining device removably mounted to the proximal end of the barrel over the end cap. Importantly, the essential one-way valve in the Liebert et al. syringe allows pressure formed within the syringe during autoclaving to be vented. Accordingly, while the Liebert et al. syringe possesses an endcap and an endcap restraining device, in view of the inclusion of the one-way valve as an essential feature of the syringe allowing pressure release, the syringe cannot be considered to be closed as asserted by the Examiner. In addition to the one-way valve, the movable plunger component of the syringe acts as a means for equalizing the pressure differential between the inside and outside of the syringe during autoclavation (see

Liebert et al. at column 3, line 22 and following) thereby prohibiting the formation of an overpressure in the syringe during the heating of the syringe as well as the formation of a vacuum during the cooling period after autoclavation. Accordingly, the essential one-way valve and movable piston of the syringe impart critical properties to the syringe, i.e., they impart pressure equalization mechanisms.

With respect to the Examiner's assertion that the syringe of Liebert et al. retains the feature of "a sufficiently high squeezability", it is asserted that nowhere in Liebert et al. is there any teaching or suggestion that the syringe "retain sufficiently high squeezability" following autoclaving. Indeed, squeezability of a syringe would not be a feature that should be preserved in a syringe subsequent to autoclaving since the pharmaceutical product located in the syringe is dispensed by pushing the plunger/piston of the syringe rather than by squeezing the syringe.

In contrast to the syringe of Liebert et al., the pharmaceutical package as defined in Claim 34 comprises a closed polypropylene bottle in which is disposed a solution or gel comprising a pharmaceutical product, wherein the solution or gel does not fill the bottle completely and some air is disposed in the bottle. The closed bottle does not possess pressure equalization mechanisms. Upon autoclaving, the package does not suffer deformation, does not shrink or explode, and retains a sufficiently high squeezability to dispense the solution or gel.

In summary, the syringe of Liebert et al. cannot be considered to be closed because the syringe is made up of components that provide essential pressure equalization mechanisms, particularly the one-way valve which releases pressure. These pressure equalization mechanisms are not available in the closed bottle recited in Claim 34. In addition, the syringe of Liebert et al. does not possess the feature of "retaining sufficiently high squeezability" following autoclavation, which is possessed by the closed bottle recited in Claim 34. Accordingly, Liebert et al., in teaching a syringe rather than a bottle and that such a syringe requires pressure equalization mechanisms, would not suggest to one skilled in the art a closed bottle that would also have the feature whereby it "retains sufficiently high squeezability" after autoclavation. Indeed, the teaching of Liebert et al. would lead one skilled in the art away from producing a closed bottle that "retains sufficiently high squeezability " as set forth in Claim 34.

In view of the lack of a suggestion in Liebert et al. of a closed bottle that retains sufficiently high squeezability after autoclavation, and the fact that one skilled in the art when reading Liebert et al. would be lead away from producing such a closed bottle, one skilled in the art would not be motivated to utilize a closed bottle as recited in Claim 34.

Czaplinkski et al. describe a generator system having a sterile disposable closure therein (see figure 1 and column 2, lines 1-48) which is utilized for sterilizing diagnostic radioneuclides. The system comprises a bottle containing a solution, which bottle is contacted in tandem with the generator system by a hypodermic needle. The generator system has a housing material that may be made of plastic or other material and which is capable of withstanding autoclaving. The solution in the bottle flows through the housing material of the generator system, is autoclaved while in the housing material of the generator system, and then is removed from the housing material of the generator system by a hypodermic needle which is connected to the bottom of the generator system and allowed to pass into an evacuate vial through conduits. The generator system is not completely sealed and the solution is not retained in or dispensed from the generator system. Accordingly, in contrast to Liebert or the presently claimed invention wherein the solution is retained in the autoclaved syringe or bottle, respectively , the solution described in Czaplinski does not remain in the autoclaved, generator housing material but instead is removed into a vial. From the discussion above, it is apparent that the generator system works in a completely different manner from the syringe of Liebert and the closed bottle recited in Claim 34. Further, while the housing material should be made with a material that is capable of withstanding autoclaving, there is no absolutely no requirement that the housing material retain sufficiently high squeezability, since the solution to be dispensed is ultimately transferred from the housing material of the generator system into a vial outside of the generator system. While the bottle recited in Claim 34 is closed, the housing material is not closed. In viewing Czaplinski et al. as a whole, it is difficult to see how the Liebert disclosure of the autoclaved, filled syringe can be combined with the Czaplinski disclosure of the generator system. Even if arguably the two references were combined the combination would not teach or suggest a closed bottle having the features as recited in Claim 34.

Accordingly, the combination of Liebert et al. and Czaplinski et al. does not make obvious Claims 34 and 41.

In view of the above, withdrawal of the rejection of Claims 34 and 41 under 35 U.S.C. §103(a) is respectfully requested.

Claims 34-35 and 41 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,842,326 (Wolf) in view of U.S. Patent 4,178,976 (Weiler et al.) and Czaplinski et al. In particular, the Examiner states:

> "Wolf discloses a pharmaceutical package as best seen in figure 1, which comprises a closed plastic bottle (5) in which is disposed a solution (2), the solution comprises a pharmaceutical product (column 5, lines 51-54), wherein the solution does not fill the bottle completely and some air is disposed in the bottle (column 6, lines 35-37), autoclaving the package (column 7, lines 4-24), after the autoclaving of the package, the package suffers no deformation, does not shrink and does not explode,

> and where the package retains a sufficiently high squeezability to dispense the solution as best seen in Figure 1, note: it is inherent that Wolf's package retains a sufficiently high squeezability to dispense the solution in as much as the applicant's claimed invention, a plastic nozzle tip (8) for dispensing the solution, a cap (7) for closing the bottle, where the bottle has walls that have a wall-thickness as, best seen in Figure 1 and note: it is inherent that the Wolf's bottle has walls that have a wall-thickness in as much as the applicant's claimed invention, a bottom portion (17). Wolf lacks after autoclaving at least 121°C and for at least 20 minutes, and the bottle is made of polypropylene. Weiler et al. teaches the use of a polypropylene bottle (60) (column 4, lines 39-64). Czaplinski et al. teaches the use of autoclaving a polypropylene at about 115°-125°C. from 20-30 minutes (column 2, lines 49-55).
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> It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the teaching of Weiler et al. into Wolf's bottle as such, in order to provide a package with a material of construction, which is pharmaceutical as well as food products can be readily packaged, as taught by Weiler et al. (column 4, lines 48-52).
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> It also would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the teaching of Czaplinski et al. into Wolf's package as such, in order to treat a material that can withstand autoclaving at a temperature 121°C for at least 20 minutes, as taught by Czaplinski et al. (column 2, lines 49-53).

Applicant respectfully disagrees with the Examiner's conclusion and submits that the combined cited references do not make obvious Claims 34-35 and 41 for the reasons stated below.

Wolf, as a whole, describes a ready pack material which is packed with syringes which can be autoclaved together (see figure 1 and column 5, lines 46-56 and column 6, lines 21-34). The ready pack consists of a syringe 3 which is filled with a liquid, gel-like or paste-like medicine, and a sealed closed pack 4 for this syringe. The syringe as shown in Figure 1 consists of a syringe body 5, the piston rod 6 and a sealing cap 7. The pack consists of a flat base 20 and a hood 21. The hood 21 is designed such that, when the syringe is inserted, its frontal wall regions 21.1 and 21.2 lie against the front side of the pressure disk 15 and the front side of the sealing cap 7, respectively (see Figure 1 and column 6, lines 21-34). Wolf indicates in column 6, lines 34-43, that upon heating the pack the air bubbles existing in the interior of the syringe body 5 cause a thermal length expansion or build-up of interior pressure. This can push the piston rod and the sealing cap away from the syringe body, so that the medication could exit in an undesired manner. The ejection of the medicine by the interior pressure is at least partially prevented by the pack itself taking up the stress due to the length expansion of the syringe. In addition, the sealing cap 7 is placed on the cylinder discharge channel body 8 so as to be movable lengthwise to a predetermined extent, without the medication inside the syringe being able to exit from the discharge channel 9 when the sealing cap moves by this predetermined path. Accordingly, the interior pressure building up in the syringe is counteracted by the pack itself and a movable sealer cap disposed on the syringe. Therefore the syringe of Wolf has pressure equalization mechanisms provided by the pack and the sealing cap.

With respect to the Examiner's statement that "it is inherent that Wolf's package retains a sufficiently high squeezability to dispense the solution in as much as applicant's claimed invention...." it is respectfully submitted that this statement is incorrect. Nowhere in Wolf is there a teaching or suggestion that the syringe retain sufficiently high squeezability after autoclavation. Indeed, as explained above for the syringe of Liebert et al., the syringe of Wolf possesses a piston rod, which piston rod is utilized to eject the medication from the syringe. The syringe itself is not squeezed to eject the medicine. Accordingly, it is not inherent that the syringe retain a sufficiently high squeezability to dispense the solution.

The present invention as defined in Claim 34 recites a bottle which is completely different from the combination pack/syringe of Wolf. The bottle recited in claim 34 does not have a movable piston as is required in the syringe of Wolf to eject medication out, but instead the bottle must be squeezed to eject/dispense the medication. Further, the bottle recited in Claim 34 is closed and has no means for equalizing pressure differentials between the inside and outside of the bottle when autoclaved, whereas the combination pack/syringe of Wolf possesses pressure equalization mechanisms. Accordingly, the syringe of Wolf alone or combined with the pack of Wolf is not equivalent to the bottle recited in Claim 34.

Weiler et al., as a whole, describes a method and apparatus for manufacturing a dispenser container that can be readily pierceable for draining. There is no teaching or suggestion of autoclaving the container or that such a container retain sufficient squeezability. Indeed, Weiler makes clear that to set the configuration of the dispenser it must be chilled to a temperature below the softening temperature of a thermoplastic material (see column 6, lines 21-27). Accordingly, it is not seen how the disclosure of Wolf concerned only with autoclaving a combination pack/filled syringe is combinable with the disclosure of Weiler et al. which is only concerned with manufacturing a dispenser container.

Czaplinski et al. has been discussed above. It is not seen how the housing system described in Czaplinski can be combined with the combined pack/syringe of Wolf and the Weiler et al. apparatus, nor would such a combination produce the closed bottle having the recited features as set forth in Claim 34.

Accordingly, the combination of cited references does not makes obvious Claims 34-35 and 41. In view of the above, withdrawal of the rejection of Claims 34-35 and 41 under 35 U.S.C. §103(a) is respectfully requested.

Claims 36-40 and 42 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Wolf in view of Weiler and Czaplinski et al. as applied to Claim 35 above and further in view of U.S. Patent No. 5,033,252 (Carter).

In particular, the Examiner states:

> "Wolf-Weiler et al.-Czaplinski et al. combination has all the features of the claimed invention except for the bottle comprises a neck portion that includes an externally threaded portion and the cap has internal threads. Carter's shows a polypropylene bottle (20) with a neck portion (26b) that includes an externally threaded portion and an outer rim, which defines an outlet (column 3, lines 24-27) and as best seen in Figure 2, a nozzle tip (40), a cap (22), which has internal threads (26a) for engagement with the externally threaded portion of the neck portion of the bottle as best seen in Figures 1-2.
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> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Wolf's bottle neck and nozzle tip with Carter's bottle neck, nozzle tip (40) and cap (22), in order to provide an alternate means of securing the cap onto the bottle neck for providing a product tight seal."

With respect to the rejection, since Claims 36-40 and 42 depend from independent Claim 34, the same arguments that have been proffered above in addressing the rejection of Claims 34-35 and 41 as being unpatentable over Wolf, Weiler et al, and Czaplinski et al. apply equally well to this rejection. In view of the above, withdrawal of the rejection of Claims 36-40 and 42 under 35 U.S.C. §103(a) is respectfully requested.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, he is requested to call the undersigned at the number

Respectfully submitted,

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Date: November 26, 2003